



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/137,822	08/21/98	NAESBY	M P1614-8067

HM12/0310
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EXAMINER

ENEWOLD, J
ART UNIT PAPER NUMBER

1655
DATE MAILED:

03/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/137,822	Applicant(s) NAESBY, MICHAEL	
	Examiner Jeanine A Enewold	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---|--|
| 14) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 15) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 16) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 19) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This action is in response to the papers filed January 27, 2000. Currently, claims 31-85 are pending. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.
2. Any objections and rejections not reiterated below are hereby withdrawn in favor of new grounds of rejection necessitated by amendment.
3. All previous rejections have been obviated by the amendment.

New Matter

4. Claim 31-85 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amended claims, reference to "the aggregate", "aggregate binding regions" are included. The amendment proposes that the new claim language clarifies the issue. However, the specification does not describe or discuss "aggregates". Instead the specification describes a triple stranded binding region with two independent probes C1 and C2 (pg. 18). This description does not support aggregate. The definition of aggregate recognized in Stedman's dictionary as "aggregate" is "to unite or come together in a mass or cluster". However, this definition sheds little light on the intended meaning of both "the aggregate" and "aggregate binding regions" as it pertains to the

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claimed invention. The concept of "forming aggregates" does not appear to be part of the originally filed invention. Therefore, "aggregate" constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

New Ground of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 31-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 31-85 are indefinite over the recitation "in the aggregate" because "in the aggregate" lacks antecedent basis.

B) Claims 31-85 are indefinite over the recitation "an aggregate binding region" because it is unclear what "an aggregate binding region" includes. It is unclear whether the aggregate binding region is located on A or

C. Further, it is unclear what physical and chemical feature define the aggregate binding region.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 31, 32, 34-36, 42-43, 55, 56, 58, 63-64, 69, 70, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Svinarchuk (J Biol Chem 1995 Jun 9;270(23):14068-71).

Svinarchuk teaches triple helix formation in which “the stability of double-stranded DNA is increased by the binding of the third strand”(abstract). Oligonucleotides were synthesized and labeled (Pg 14068, Col 2, Para 2). The triple helix was formed and monitored by 5% polyacrylamide gel electrophoresis (Pg 14068, Col 2, Para 2). The thermostability was monitored by a thermometer (Pg 14068, Col 2, Para 2). As seen in Figure 3, there is only one nucleic acid binding probe C in the triple stranded region, nucleic acid binding probe B is smaller than nucleic acid binding probe C, nucleic acid binding probe C has a length of at least 6, nucleic acid binding probe B is capable of having either an asymmetrical or a symmetrical base sequence, nucleic acid binding probe B is bound to nucleic acid A via Hoogsteen base pairing while nucleic acid binding probe C is bound to nucleic acid A via Watson and Crick binding, and nucleic acid binding probe C fully spans the region of nucleic acid binding probe B.

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It is noted that Svinarchuk teaches a double stranded molecule with a probe hybridized to a specific region. However, as written, the independent claims do not include specific size requirements for nucleic acid binding probe C. Therefore teachings of a double stranded molecule encompass the limitations of the claims. Furthermore, Svinarchuk teaches radiolabeling oligonucleotides and detecting (monitoring) by gel electrophoresis. Thus, Svinarchuk teaches detection of the triplex formation.

Conclusion

7. No claims are allowable.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A) Orum et al (US Pat 6,027,893)—teaches identifying nucleic acids based on triplex formation. However, Orum does not specifically teach size limitations for the nucleic acid probes required of the instant claims.

B) Vary (US Pat 5,800,984)—teaches LCR of two probes on a single stranded nucleic acid followed by denaturing and subsequent re-annealing to newly-ligated probes. The newly formed double stranded nucleic acid is then captured with a third strand of nucleic acid. Although, Vary teaches two probes hybridizing to a single nucleic acid followed by the hybridization of a probe to form a triple stranded region. The step included in the process to denature the ligated probes to re-anneal to other newly ligated probes, would not read on the claims of detecting a target nucleic acid A.

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9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Enewold whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Thursday from 7:00 AM to 4:30 PM.

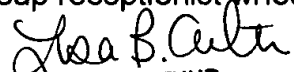
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Enewold

March 6, 2000




LISA B. ARTHUR
PRIMARY EXAMINER
GROUP 1800/600